MAY 13 2002

K010615

Special 510(k) Summary:

Proprietary Name:	Super Secur-Fit™ HA Hip Stems and Super Secur-Fit™ Plus HA Hip Stems
Common Name :	Artificial Hip Components
Classification Name and Reference:	Hip joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353
Proposed Regulatory Class :	Class II
Device Product Code :	87 MEH
For Information contact:	Jennifer Daudelin Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401 Phone: (201) 831-5379 Fax: (201) 760-8435

Description/Technological Comparison

Predicate Device Name/Catalog # Series	Subject Modifications	Resulting Subject Device Name/Catalog # Series
Secur-Fit™ HA Hip Stems (6051A series), 132° neck angle	• Change C-Taper to V40™ Taper • Trim neck diameter • Add slot for modular collar	Super Secur-Fit™ HA Hip Stems (J6051 series)
Secur-Fit™ HA Hip Stems (6052A series), 127° neck angle	• Change C-Taper to V40™ Taper • Trim neck diameter	Super Secur-Fit™ HA Hip Stems (J6052 series)
Secur-Fit™ Plus HA Hip Stems (6054A series), 127° neck angle	• Change C-Taper to V40™ Taper • Trim neck diameter	Super Secur-Fit™ Plus HA Hip Stems (J6054 series)

Intended Use

The intended use of the modified hip stems remains essentially unchanged from that of the predicate hip stems. Like the predicate devices, the subject devices are single-use components intended for cementless fixation within the prepared canals of patients requiring hip arthroplasty. Unlike the predicate devices, however, the subject devices feature a V40™ Taper, and are

therefore intended only for assembly to mating, commercially available Howmedica V40™ Femoral Heads. Note, also, that the subject hip stems are not recommended for use with size +16mm V40™ Femoral Heads.

Testing Summary

Neck fatigue testing was performed in accordance with ISO 7206-6.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2002

Ms. Jennifer A. Daudelin
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401

Re: K020615
Trade/Device Name: Modification to Secur-Fit™ HA and Secur-Fit™ Plus HA Hip Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH
Dated: April 22, 2002
Received: April 23, 2002

Dear Ms. Daudelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020615

Device Name: Modification to Secur-Fit™ HA Hip Stems and Secur-Fit™ Plus HA Hip Stems (Super Secur-Fit™ HA Hip Stems and Super Secur-Fit™ Plus HA Hip Stems)

The subject hip stems are single-use devices intended for use in total hip replacement. They are designed for cementless fixation. They are intended for mechanical assembly to mating Howmedica V40™ Femoral Heads (excluding size +16mm (XX Long) V40 Femoral Heads).

Indications:

The indications for use of total hip replacement prostheses include:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Revision procedures where other treatments or devices have failed, and
- Treatment of nonunion, femoral femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-The-Counter Use No (Per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020615